

# **EXHIBIT A**

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION**

**IN RE: NATIONAL PRESCRIPTION  
OPIATE LITIGATION**

This document relates to:  
*The County of Summit, Ohio, et al. v. Purdue  
Pharma L.P., et al.*  
Case No. 18-op-45090

and

*The County of Cuyahoga v. Purdue Pharma  
L.P., et al.*  
Case No. 1:18-op-45004

MDL No. 2804

Hon. Judge Dan A. Polster

**SUMMARY SHEET FOR  
DEFENDANTS' OPPOSITION TO TRACK ONE PLAINTIFFS'  
MOTION FOR PARTIAL SUMMARY ADJUDICATION OF  
DEFENDANTS' DUTIES UNDER THE CONTROLLED SUBSTANCES ACT  
[DEFS' CSA "DUTIES" BRIEF]**

The attached opposition explains that Plaintiffs are not entitled to partial summary adjudication as to Defendants' purported "duties" under the CSA. Plaintiffs are wrong about what the CSA and its regulations require.

The CSA and its regulations do not create legal "duties" that trigger automatic liability as Plaintiffs propose. The CSA's provision regarding registrants' "maintenance of effective controls against diversion" is instead one of several factors enumerated in the statute that DEA is to consider when DEA determines whether it would be "consistent with the public interest" to issue, suspend, or revoke a federal registration. Nor do DEA regulations stating that registrants "provide effective controls and procedures to guard against theft and diversion of controlled substances" create the

“duties” that Plaintiffs propose to trigger automatic liability. Rather, the regulations specify that, to determine whether a registrant has provided effective controls, DEA is to use a set of security requirement regulations, including a suspicious order regulation, and that “[s]ubstantial compliance” with those regulations “may be deemed sufficient” by “the Administrator after evaluation of the overall security system and needs of the applicant or registrant.” The regulations’ sole reference to “suspicious orders” provides only for registrants to identify and inform DEA of suspicious orders—defined as orders of “unusual size,” “unusual frequency,” or “deviating substantially from a normal pattern.” It does not include a requirement that no such orders be shipped.

The limited scope of the CSA and its regulations is not—and legally cannot be—expanded by the two DEA “Dear Registrant” letters or the two revocations of non-party companies’ registrations (*Southwood* and *Masters*) that Plaintiffs cite. The letters do not have the force or effect of law because they are, at most, interpretive materials, not notice-and-comment rules. And the registration revocations cited by Plaintiffs address situations of individual companies involving case-specific matters that do not bind other registrants, including any of the Defendants.